CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19012/S-053

Name: Motrin® IB (ibuprofen) Tablets

Sponsor: McNeil Consumer Healthcare

Approval Date: July 30, 2015

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new analytical testing site for testing raw materials.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19012/S-053

APPROVAL LETTER

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.
Attention: Samuel Herald, M.S.
Associate Director, Regulatory Affairs
7050 Camp Hill Road, Mail Stop 111
Fort Washington, PA 19034

Dear Mr. Herald:

Please refer to your Supplemental New Drug Application (sNDA) dated January 30, 2015, received January 30, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MOTRIN®IB (ibuprofen) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for new analytical testing site, (b) (4) for testing raw materials.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402-3777.

Sincerely,

Ramesh Raghavachari -S

Digitally signed by Ramesh Raghavachari -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300211793, cn=Ramesh Raghavachari -S
Date: 2015.07.30 13:17:07 -04'00'

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities 1
Office of Lifecycle Drug Products
Center for Drug Evaluation and Research

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CHEMISTRY REVIEWS

Review of Chemistry, Manufacturing and Controls

Chemist's Review No. 1	1. Organization OND Division DNCE	2. NDA Numbers 19012

3. Name and Address of the Applicant	4. Supplement Numbers: S053 **Letter Date**: 01/30/2015 **Stamped Date**: 01/30/2015 **Type:** CBE-30 **Due Date:** 07/30/2015 **Assignment Received Date:** 02/18/2015
McNeil Consumer Healthcare Division of McNeil-PPC, Inc. 7050 Camp Hill Road Fort Washington, PA 19034-2299	

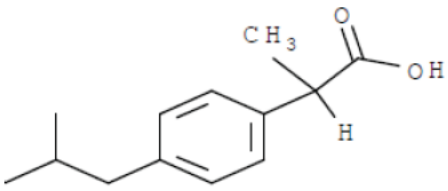
5. Established Name	6.Proprietary Name	7. Amendments, Report, Date
Ibuprofen	Motrin® IB	

8. Supplement Provides for:
New analytical testing site, [redacted] (b) (4), for testing raw materials

9. Indication(s) for Use:	10. How Dispensed	11a. Related Documents
Temporarily relieves minor aches and pains due to headache, minor pain of arthritis, backache, menstrual cramps, muscular aches, toothaches, the common cold and temporarily reduces fever	OTC	

12. Dosage Form	13. Strengths	11b. Submission Media
Tablet	200 mg	Electronic

14. Chemical Name and Structure
Ibuprofen, (*RS*)-2-(4-(2-methylpropyl)phenyl)propanoic acid
Molecular Formular: $C_{13}H_{18}O_2$
Molecular Weight: 206.28



15. Comments
The proposed [redacted] (b) (4) was not submitted to facility inspection since they were proposed to perform testing of raw materials.
McNeil Consumer Healthcare (McNeil) affirms that:

- The test methods used at [redacted] (b) (4) are approved in the NDA.
- There are no post-approval commitments relating to the test methods.
- [redacted] (b) (4) has the capability to perform the testing.
- [redacted] (b) (4) had a satisfactory current good manufacturing practice (CGMP) inspection by the FDA in [redacted] (b) (4) where no critical observations were issued.

The applicant has made a statement that meets the requirements set in Guidance for Industry, PAC-ATLS: Postapproval Changes-Analytical Testing Laboratory Sites, April 1998 . Proposed site is acceptable to perform intended testing procedures.

16. Conclusion and Recommendation
Recommended for Approval

17. Name	18. Reviewer's Signature	19. Date Completed
Ping Jiang-Baucom	See appended electronic signature sheet	07/19/2015

Ping Jiang-baucom -S

Digitally signed by Ping Jiang-baucom -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000342556, cn=Ping Jiang-baucom -S
Date: 2015.07.20 08:08:46 -04'00'

Ramesh Raghavachari -S

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Initial Quality Assessment - OLDP Division of Post-Marketing Activities I

NDA: 19012	**NME:** Yes ☐ No ☒	**Original NDA Approval Date:** 5/18/1984
Supplement: 53	**Applicant:** MCNEIL CONSUMER PRODUCTS CO DIV MCNEILAB INC	**Product:** MOTRIN MIGRAINE PAIN, SUSTAINED ACTION, COATED
Clinical Division: DNCP		
Managed by: OND ☐ **OPQ** ☒		
Receipt Date: January 30, 2015		**PDUFA Goal Date:** July 30, 2015
Proposed changes: New analytical testing site for testing raw materials		
Submitted as: Paper ☐ Electronic ☒		
Submitted Category: CBE-0 ☐ CBE-30 ☒ PA ☐		**Final Category:** CBE-0 ☐ CBE-30 ☒ PA ☐
Expedited Review Requested: Yes ☐ No ☒	**Drug Shortage:** Yes ☐ No ☒	**Bundled Supplements:** Yes ☐ No ☒

Facility Entry/Consults Needed:

Facility Entry: ☐ Micro: ☐ Biopharm: ☐ Pharm/tox: ☐

Statistics: ☐ CDRH: ☐ OPF: ☐ DMEPA: ☐

Other:

DMF Review: ☐

Comments: The site will not be submitted for inspection based on IQP 5102 version 2.

QAL: Don Klein	**Date:** 2/18/15
Assigned Reviewer: Ping Jiang-Baucom	**RBPM:** Teicher Agosto